2011 Pediatric Immunization Update

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Disclosures

Andrew Kroger is a federal government employee with no financial interest or conflict with the manufacturer of any product named in this presentation

Andrew Kroger will not discuss a vaccine not currently licensed by the FDA

Disclosures

Andrew Kroger will discuss off-label uses meningococcal conjugate vaccine (MCV4) and human papillomavirus vaccine (HPV)

What's New in Immunization

Meningococcal Conjugate Vaccine

Human Papillomavirus Vaccine

Measles Outbreaks

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Persons at Highest Risk of Meningococcal Disease or Suboptimal Vaccine Response

<u>Complement deficiency</u>

- High-risk of disease
- Very high antibody titer required to compensate for complement deficiency

<u>Asplenia</u>

- High-risk of disease
- evidence of suboptimal response

Persons with Suboptimal Vaccine Response

HIV infection

– evidence of suboptimal response

Single dose primary series may not be sufficient to confer protection for persons with these high-risk conditions

New MCV4 Recommendations

Administer 2 doses of MCV4 at least 8 weeks apart to persons with persistent complement component deficiency and anatomic or functional asplenia, and 1 dose every 5 years thereafter

MMWR 2011;60(No. 3):72-6.

New MCV4 Recommendations

HIV infection is not an indication for MCV4 vaccination

However, some persons with HIV infection should receive MCV4 (adolescents, some international travelers, microbiologists, etc)

Persons with HIV infection who are vaccinated with MCV4 should receive 2 doses at least 8 weeks apart

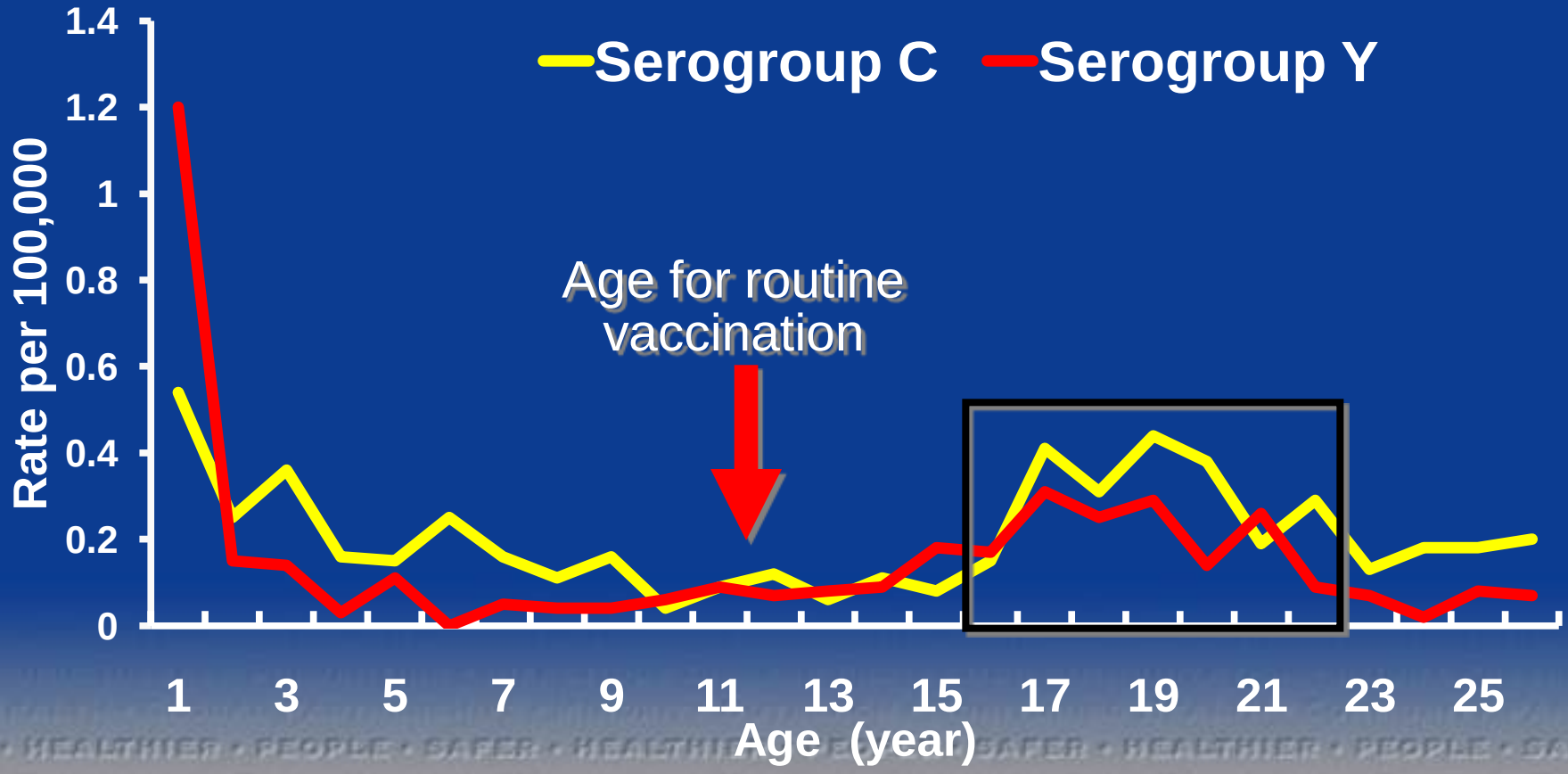
MMWR 2011;60(No. 3):72-6.

New MCV4 Recommendations

Persons with complement component deficiency, asplenia and HIV who previously received 1 dose should receive a second dose at the earliest opportunity

MMWR 2011;60(No. 3):72-6.

Rates of Meningococcal Disease (C and Y) by Age, 1999-2008



Active Bacterial Core surveillance (ABCs), 1998-2008

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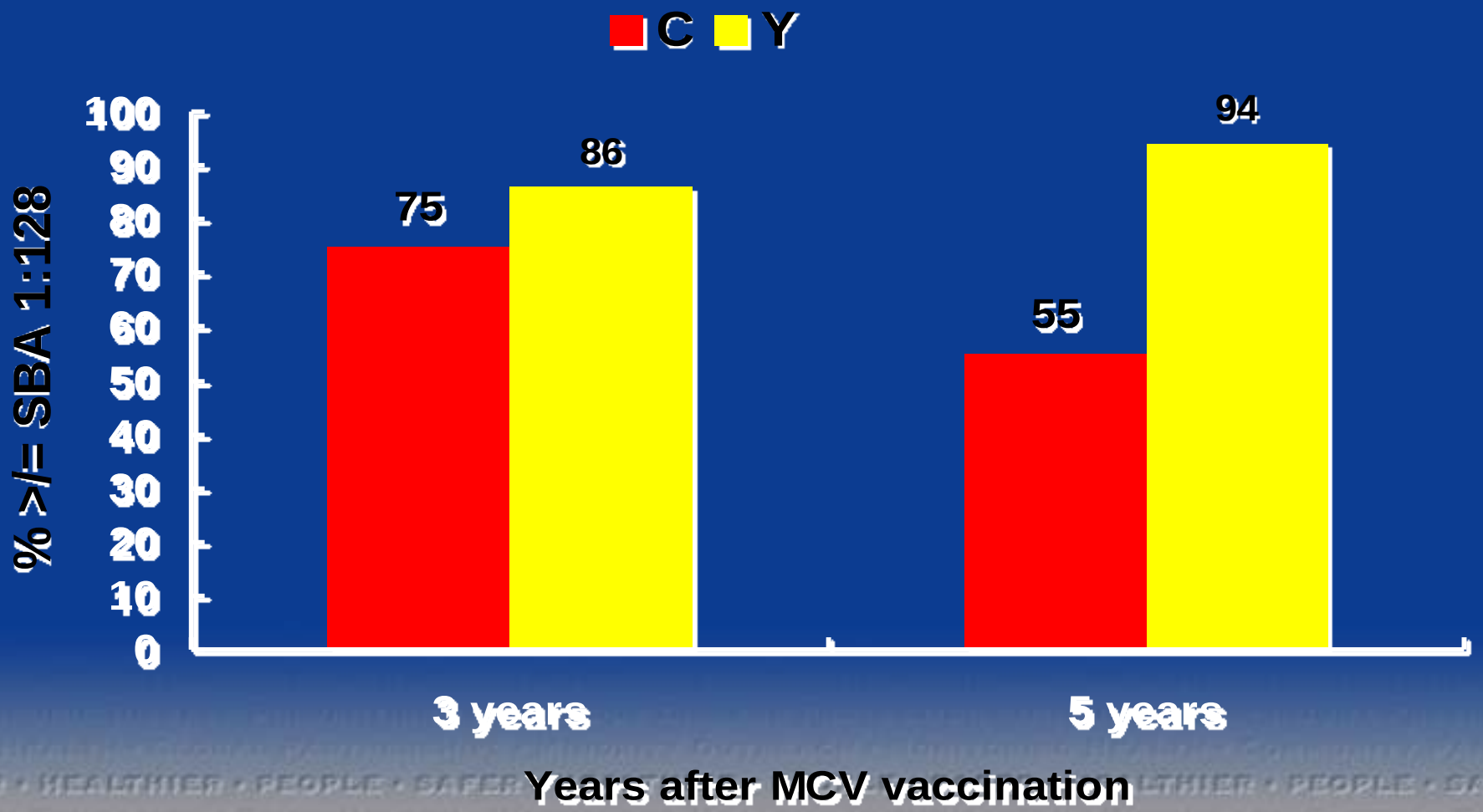
Meningococcal Conjugate (MCV4) Routine Revaccination

In its 2005 recommendations for MCV, ACIP made no recommendation about revaccination pending the availability of additional data

Serologic data are now available from the manufacturer that show significant decline in antibody 3-5 years after vaccination although few "breakthrough" cases have been reported

MMWR 2009;58(No. 37):1042-3

Seroprotection Rates Following MCV Vaccination



MMWR 2009;58(No. 37):1042-3

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New MCV4 Recommendations*

- administer MCV4 at age 11 or 12 years with a booster dose at 16 years of age
- administer 1 dose at age 13 through 15 years if not previously vaccinated
- for persons vaccinated at age 13 through 15 years administer a 1-time booster dose is recommended, preferably at or after 16 through 18 years of age

*off-label recommendation. *MMWR* 2011;60(No. 3):72-6.

New MCV4 Adolescent Vaccination Recommendations

The minimum interval between doses is 8 weeks

A booster dose is not recommended for healthy persons if the first dose is administered at 16-21 years of age

A booster dose is not recommended for healthy persons 19 years or older even if the first dose is administered at 11-15 years of age – may be considered if entering college

The booster dose should always be MCV4 (not MPSV4)

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MMWR 2011;60(No. 3):72-6.

MCV Revaccination Recommendations*

Other high-risk persons recommended for revaccination

- microbiologists with prolonged exposure to *Neisseria meningitidis*
- frequent travelers to or persons living in areas with high rates of meningococcal disease

Revaccinate every 5 years as long as the person remains at increased risk

Every 3 years if first dose given between 2 through 6 years of age

- MCV4 for persons 2 through 55 years of age
- MPSV for persons 56 years and older

*off-label recommendation. *MMWR* 2009;58(No. 37):1042-3

Human Papillomavirus

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HPV Prevalence: Population Estimates, U.S.

20 million people are infected

6.2 million new infections each year

> 50% of sexually active men & women acquire genital HPV infection

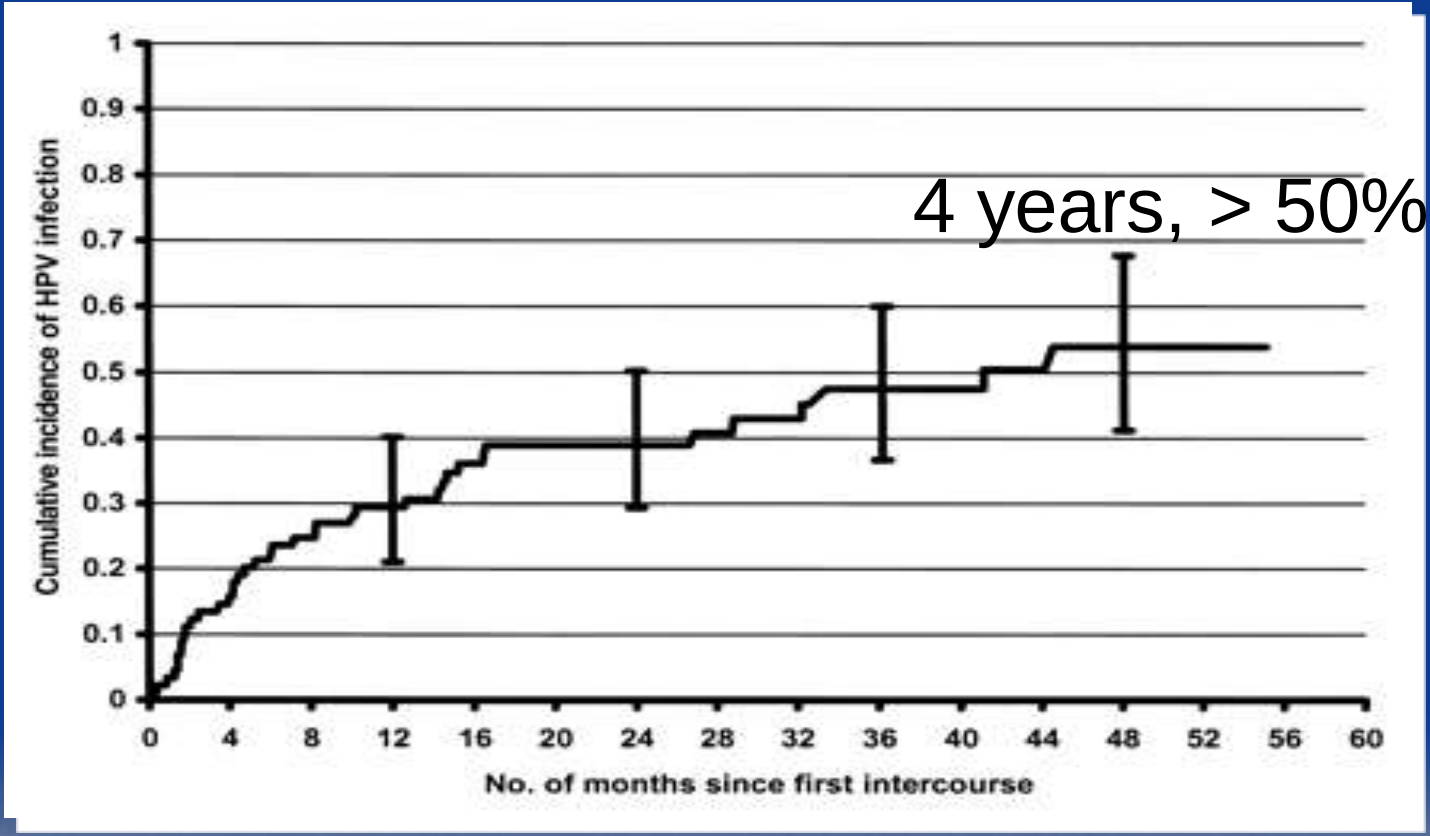
74% of new infections occur in persons 15 – 24 years of age

W. Cates, STD April 1999, Weinstock, Perspectives on Sexual and Reproductive Health 2004, Koutsky Am J Med 1997

HPV-Associated Disease

Type	Women	Men
16/18	70% of Cervical Cancer 70% of Anal/genital Cancer	70% of Anal Cancer
6/11	90% of Genital Warts 90% of RRP lesions	90% of Genital Warts 90% of RRP lesions

Cumulative Incidence of Any HPV Infection
Months after sexual initiation



Am J Epidemiol, 2003;157(3):218-26

Cervical Cancer Disease Burden in the United States

The American Cancer Society estimates that in 2009

- 11,270 new cervical cancer cases
- 4,070 cervical cancer deaths

Almost 100% of these cervical cancer cases were caused by one of the 40 HPV types that infect the mucosa

Source: American Cancer Society
www.cancer.org/

Human Papillomavirus Vaccines

Two HPV vaccines are available

Both vaccines contain noninfectious HPV L1 major capsid protein

L1 protein is produced using recombinant technology

Both vaccine contain an aluminum-based adjuvant

Neither vaccine contains preservative or antibiotic

HPV Vaccines

HPV4 (Gardasil, Merck)

- contains HPV types 16, 18, 6 and 11
- approved for the prevention of cervical, vaginal and vulvar cancers (in females) and genital warts (in females and males)

HPV2 (Cervarix, GSK)

- contains HPV types 16 and 18
- approved for the prevention of cervical cancers in females

HPV Vaccination Schedule

Routine schedule is 0, 1-2, 6 months

Minimum intervals

- 4 weeks between doses 1 and 2
- 12 weeks between doses 2 and 3
- 24 weeks between doses 1 and 3

Administer at the same visit as other age-appropriate vaccines – Tdap, MCV

HPV Vaccine Efficacy

	HPV4 16-26 y/o females		HPV2 15-25 y/o females	
	N	VE	N	VE
HPV 16/18 CIN2/3 or AIS	8,493	98%	7,344	93%
HPV 6/11 EGL	6,932	99%	--	--

Manufacturer clinical trial data

Vaccine Efficacy for HPV 6,11,16,18-Related External Genital Lesions (EGL) for Boys and Men 16 Through 26 Years of Age

Endpoint	Vaccine Group (N=1397)	Placebo Group (N=1408)	Efficacy (%)
HPV 6/11/16/18-related EGL	3	31	90
HPV 6/11/16/18-related condyloma	3	28	89
HPV 6/11/16/18-related PIN* 1/2/3	0	3	100*

*Penile/perineal/perianal intraepithelial neoplasia (PIN) grades 1/2/3; too few cases identified to reach statistical significance. Merck data.

Human Papillomavirus Vaccines

High efficacy among females without evidence of infection with vaccine HPV types

No evidence that the vaccine had efficacy against existing disease or infection

Prior infection with one HPV type did not diminish efficacy of the vaccine against other vaccine HPV types

HPV4 reduces the risk of genital warts in males but reduction in anogenital cancer risk among males has not yet been demonstrated

HPV Vaccine Interchangeability

No data on schedules that include both HPV2 and HPV4

Response to types 16 and 18 likely to be similar when HPV2 and HPV4 used in the same series

Protection against types 6 and 11 probably reduced if fewer than 3 doses of HPV4 received

Use same vaccine for all 3 doses whenever possible

HPV Vaccine "Special Situations"

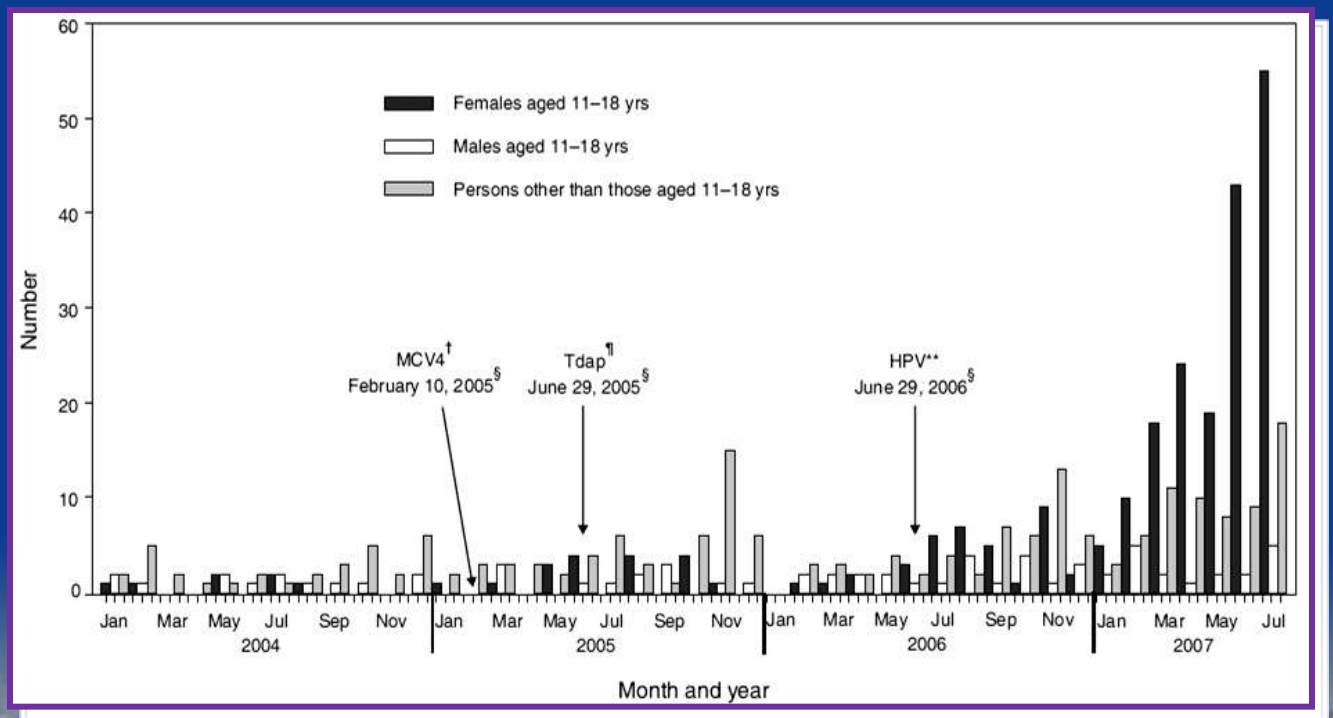
Vaccine can be administered to females with:

- equivocal or abnormal Pap test
- positive HPV DNA test
- genital warts
- immunosuppression
- breastfeeding

MMWR 2010;59(No. 20):626-9

Number of Postvaccination Syncope* Episodes Reported to the Vaccine Adverse Event Reporting System

By month and year report – United States, January 1, 2004 - July 31, 2007



MMWR 2008;57(No. 17):457-60

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Prevention of Syncope After Vaccination

Vaccine providers should strongly consider observing patients for 15 minutes after they are vaccinated

If syncope develops, patients should be observed until symptoms resolve

Clinicians should be aware of presyncopal manifestations (weakness, dizziness, pallor, etc) and take appropriate measures to prevent injuries if they occur

MMWR 2008;57(No. 47):457-60; *MMWR* 2006;55(RR-15):19

Cervical Cancer Screening

Cervical cancer screening – no change

- 30% of cervical cancers caused by HPV types not prevented by the quadrivalent HPV vaccine
- Vaccinated females could subsequently be infected with non-vaccine HPV types
- Sexually active females could have been infected prior to vaccination

Providers should educate women about the importance of cervical cancer screening

MMWR 2007;56(RR-2):1-24

Measles

Over 80 imported cases this year

Epidemics in Spain, France, Belgium, Macedonia

MMR

A dose is recommended for travelers between 6 through 12 months of age

Does NOT count toward the two dose routine series

CDC Vaccines and Immunization Contact Information

Telephone
800.CDC.INFO

(for patients and parents)

Email
nipinfo@cdc.gov

(for providers)

Website
www.cdc.gov/vaccines/

Vaccine Safety
www.cdc.gov/vaccinesafety/

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